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10/528,992	01/10/2006	Nobuyuki Yoshida	0020-5361PUS1	6388
2292	7590	06/08/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			FRONDA, CHRISTIAN L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/528,992	YOSHIDA ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 May 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 - 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2 and 4 is/are rejected.
- 7) Claim(s) 3 and 5 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 March 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/21/05.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

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DETAILED ACTION

1. Applicant's election with traverse of Invention 1 (claims 1-5) in the reply filed on 05/21/2007 is acknowledged. The traversal is on the ground(s) that the amino acid sequence of AAW69251 does not, either expressly or inherently, anticipate the claimed fructosylamine oxidase. This is not found persuasive for reason of record as further explained below.

According to 1893.03(d) [R-3] Unity of Invention:

"Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371."

According to MPEP 1850 [R-5] Unity of Invention Before the International Searching: "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4)".

The specification states that "... the recombinant FAOs of the present invention obtainable in this manner are not limited to those having the amino acid sequences shown in SEQ ID Nos. 4 and 6, and rather encompass proteins having an amino acid sequence derived from the said sequences according to a conventional manner and fragments of the amino acid sequences shown in SEQ ID Nos. 4 and 6" (see p. 13, lines 21-27).

Thus, independent claim 1 of Invention 1 (main claim) encompasses any fructosylamine oxidase of any amino acid sequence and structure since the claim recites that the enzyme is "derived" from *Fusarium proliferatum* which expands the scope of the claim. This is the same or corresponding technical feature shared among Inventions 1-3 as stated in the previous Office Action.

As stated previously, this technical feature has already been taught in the prior art by Accession AAW69251 (Asahi Kasei Kogyo KK, 28-OCT-1998; reference of record). Accession AAW69251 teaches a fructosylamine oxidase that has 92.4% amino acid identity to the claimed SEQ ID NO: 6 (see attached alignment). Furthermore, the taught fructosylamine oxidase has a molecular weight of about 49 kDa when estimated by SDS-PAGE since the taught fructosylamine oxidase has 440 amino acid residues. Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-3 are not so linked as to form a single general inventive

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concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL. Claims 6-11 have been withdrawn from consideration as drawn to a non-elected invention.

2. Claims 1-5 are under consideration in this Office Action.

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. The information disclosure statement filed 03/25/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-5 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over fructosylamine oxidase enzymes as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated fructosylamine oxidase" or "purified fructosylamine oxidase ". See MPEP 2105.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated fructosylamine oxidase comprising the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The specification states that "... the recombinant FAOs of the present invention obtainable in this manner are not limited to those having the amino acid sequences shown in SEQ ID Nos. 4 and 6, and rather encompass proteins having an amino acid sequence derived from the said sequences according to a conventional manner and fragments of the amino acid sequences shown in SEQ ID Nos. 4 and 6" (see p. 13, lines 21-27). Thus, the nature and breadth of the claims encompass any fructosylamine oxidase of any amino acid sequence for which no structure is apparent since the claims recite that the enzyme is "derived" from *Fusarium proliferatum*.

The specification provides guidance and working examples for an isolated fructosylamine oxidase consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. However, the specification does not provide guidance, prediction, and working examples for making any fructosylamine oxidase of any amino acid sequence for which no structure is apparent that is "derived" from *Fusarium proliferatum*. Thus, an undue amount of trial and error experimentation must be performed where such experimentation involves searching and screening a vast number of biological sources for any fructosylamine oxidase having the recited properties.

Alternatively, trial and error experimentation must then be performed to search and screen for specific amino acid residues to change in SEQ ID NO: 4 or SEQ ID NO: 6 (e.g., amino

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acid deletion, insertion, substitution, and combinations thereof) which will result in a derivative that has not lost fructosylamine oxidase enzymatic activity.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid sequence of the claimed fructosylamine oxidase "derived" from *Fusarium proliferatum*. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

9. Claim 1, 2, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims drawn to a genus of fructosylamine oxidase of any amino acid sequence for which no structure is apparent since the claims recite that the enzyme is "derived" from *Fusarium proliferatum*. The scope of the genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid sequences, structures, and/or biological functions. Furthermore, the genus is highly variable because a significant number of structural and biological differences between genus members exist.

The specification discloses an isolated fructosylamine oxidase consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. However, the specification does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of the genus. The specification fails to provide a written description of representative fructosylamine oxidase other than the fructosylamine oxidase consisting of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of each genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical

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and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the claimed genus of fructosylamine oxidase of any amino acid sequence for which no structure is apparent.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession AAW69251 (Asahi Kasei Kogyo KK, 28-OCT-1998; reference of record).

The specification states that "... the recombinant FAOs of the present invention obtainable in this manner are not limited to those having the amino acid sequences shown in SEQ ID Nos. 4 and 6, and rather encompass proteins having an amino acid sequence derived from the said sequences according to a conventional manner and fragments of the amino acid sequences shown in SEQ ID Nos. 4 and 6" (see p. 13, lines 21-27). Thus, claim 1 encompasses any fructosylamine oxidase of any amino acid sequence and structure since the claim recites that the enzyme is "derived" from *Fusarium proliferatum*.

Accession AAW69251 (Asahi Kasei Kogyo KK, 28-OCT-1998; reference of record) teach a fructosylamine oxidase that has 92.4% amino acid identity to the claimed SEQ ID NO: 6 (alignment enclosed in the previous Office Action dated 04/20/2007). The taught fructosylamine oxidase has a molecular weight of about 49 kDa when estimated by SDS-PAGE since the taught fructosylamine oxidase has 440 amino acid residues. Furthermore, the taught fructosylamine oxidase is expected to have the recited optimum pH, optimum temperature, active on fructosyl valine, and not detectably active on fructosyl lysine since it has a high amino acid identity of 92.4% to the claimed SEQ ID NO: 6 and has a molecular weight of about 49 kDa when estimated by SDS-PAGE.

Since the Patent Office does not have the facilities for examining and comparing the

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claimed fructosylamine oxidase to the fructosylamine oxidase taught by Accession AAW69251, the burden is on applicant to show that the prior art fructosylamine oxidase is different from the claimed fructosylamine oxidase. See *In re Best*, 562 F.2d 1252, 195 USPQ 430(CCPA 1977). Thus, the reference teachings anticipate the claimed invention.

Conclusion

12. No claim is allowed.
13. Claims 3 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.
15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER